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Bayer Corporation, and Bayer HealthCare LLC

[Additional Counsel on Signature Page]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

KATHLEEN GEISSE, Ph.D., CURTIS ULLESEIT and LISA WEHLMANN,

Plaintiffs,

vs.

BAYER HEALTHCARE PHARMACEUTICALS INC.; BAYER PHARMA AG; formerly known as BAYER SCHERING PHARMA AG; BAYER

Case No. 17-cv-07026-JD

JOINT CASE MANAGEMENT STATEMENT & [PROPOSED] ORDER

Date: March 1, 2018
Time: 10:00 AM
Courtroom: 11, 19th Floor
Judge: Hon. James Donato

CORPORATION; BAYER HEALTHCARE LLC; MCKESSON CORPORATION, MERRY X-RAY CHEMICAL CORPORATION; and DOES 1 through 20,

Defendants.

Defendants Bayer HealthCare Pharmaceuticals, Inc., Bayer Corporation, Bayer HealthCare LLC (collectively, "Bayer"), McKesson Corporation, Merry X-Ray Chemical Corporation (collectively "Distributing Defendants"), and plaintiffs Kathleen Geisse, Curtis Ulleseit, and Lisa Wehlmann (collectively "Plaintiffs") (all aforementioned parties collectively "the Parties") jointly submit this JOINT CASE MANAGEMENT STATEMENT & PROPOSED ORDER pursuant to the Standing Order for All Judges of the Northern District of California dated January 17, 2017 and Civil Local Rule 16-9.

1. Jurisdiction & Service

A. Subject Matter Jurisdiction

i. Plaintiffs' Position

Plaintiffs contend that the Court lacks diversity subject matter jurisdiction.

ii. Bayer's Position

Bayer contends that the Court has subject matter jurisdiction over this action[1] under 28 U.S.C. § 1332(a) because there is the required diversity of citizenship between each of the Plaintiffs and each properly joined defendant and the amount in controversy exceeds the sum of $75,000, exclusive of costs and interest for the reasons set forth in the Notice of Removal filed on December 8, 2017. *See Mississippi ex rel. Hood v. AU Optronics Corp.*, 134 S. Ct. 736, 745 (2014) (It is settled law that "a plaintiff may not keep a case out of federal court by fraudulently naming a nondiverse defendant."); *Goldberg v. CPC Int'l, Inc.*, 495 F. Supp. 233, 239 (N.D. Cal. 1980) ("Courts have

[1] Bayer additionally contends that the court lacks subject matter jurisdiction over Plaintiffs' claims brought under California's Consumer Legal Remedies Act, which Plaintiffs have represented they will dismiss but have not formally done so to date. Plaintiffs lack standing to seek injunctive relief because they do not face "a real or immediate threat of . . . injury" from the future conduct they seek to enjoin. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1114 (9th Cir. 2013).

found joinder to be fraudulent where there is no reasonable basis in fact or colorable ground supporting the claim against the joined defendant, or no real intention in good faith to prosecute the action against that defendant or seek a joint judgment.").

B. Personal Jurisdiction and Venue

i. Plaintiffs' Position

Plaintiffs have alleged, and will prove through discovery, sufficient contacts between Bayer and California such that this Court can properly exercise Specific Personal Jurisdiction over the Bayer entities, and other defendants named in the Complaint. Specifically, Plaintiffs allege that Bayer conducted clinical trials of Magnevist within California, which became part of an unbroken chain of events leading to Plaintiffs' injuries. See *Dubose v. Bristol-Myers Squibb Co.*, No. 17- cv-00244, 2017 U.S. Dist. LEXIS 99504 (N.D. Cal. June 27, 2017).

Two of the defendants named in Plaintiffs' Complaint are headquartered and located in California. Defendant McKesson Corporation has its headquarters in San Francisco, and Defendant Merry X-Ray Chemical Corporation is in San Diego, California. Because McKesson is located in San Francisco, venue is appropriate here.

ii. Bayer's Position

As stated in its answer, Bayer preserves its personal jurisdiction and venue challenges. *See, e.g., Ear v. Empire Collection Authorities, Inc.*, No. 12-1695-SC, 2012 WL 3249514, at *2 (N.D. Cal. Aug. 7, 2012) ("Rule 12(h) explicitly permits certain negative defenses to be pled in an answer, specifically, the defenses enumerated in Rule 12(b)(2)-(5) [including] lack of personal jurisdiction [and] improper venue…").

C. Service

All named parties have been served, with the exception of Bayer Pharma AG, which Plaintiffs dismissed from the case.

2. Facts

A. Brief Statement of Facts

i. Plaintiffs' Position

Plaintiffs had normal kidney function prior to injection of a linear gadolinium-based contrast agent during one or more MRIs/MRAs. Unbeknownst to Plaintiffs, they developed Gadolinium Deposition Disease ("GDD") soon thereafter. GDD manifests when gadolinium in the contrast dye breaks free from its chelate (protective coating) and deposits in the brain, organs, tissue, and bones of the patient following an MRI or an MRA. The linear agents are less stable than the macrocylic agents and are therefore more likely to dissociate and deposit gadolinium in the body. Gadolinium is a highly toxic heavy metal. The only known route for gadolinium to enter the human body is injection of a gadolinium-based contrast agent ("GBCA").

During the years that Defendants manufactured, marketed, distributed, sold, and administered gadolinium-based contrast agents, there have been numerous case reports, studies, assessments, papers, peer reviewed literature, and other clinical data that have described and/or demonstrated gadolinium retention in connection with the use of gadolinium-based contrast agents.

Neither Plaintiffs nor their healthcare providers were warned that linear GBCAs were unstable and could deposit gadolinium in the bodies of patients with normal kidney function. A black box warning was added to the labeling for GBCAs in 2007, however that warning only applied to patients with abnormal renal function.

In July of 2015, and in direct response to a Mayo Clinic study's findings, the FDA issued a new public safety alert stating that the FDA is evaluating the risk of brain deposits from repeated use of gadolinium-based contrast agents use in MRI's.

In March of 2017, the European Medicines Agency's Pharmacovigilance Risk Assessment Committee ("PRAC") recommended the suspension of marketing authorizations for linear gadolinium contrast agents because of evidence that gadolinium may be retained.

In July of 2017, the European Medicines Agency confirmed that there is convincing evidence of gadolinium retention. They recommended suspension of linear agents, except in a few very specific circumstances.

In September of 2017, the FDA's medical advisory committee voted 13 to 1 in favor of adding a warning on labels that gadolinium can be retained in some organs, including in the brain, even in patients with healthy kidneys.

In November of 2017, Japan's Ministry of Health, Labour and Welfare required label changes warning of possible gadolinium retention in the linear GBCAs: Omniscan (manufactured by GE Healthcare); Magnevist (manufactured by Bayer); and Eovist (manufactured by Bayer).

In December of 2017, the FDA announced that it is requiring a new class warning and other safety measures for all gadolinium-based contrast agents concerning gadolinium remaining in patients' bodies, including the brain, for months to years after receiving these drugs.

In February of 2018, the United Kingdom's pharmaceutical regulatory agency, the Medicines & Healthcare Products Regulatory Agency, issued a recall of all Magnevist (manufactured by Bayer) and all Omniscan (manufactured by GE Healthcare).

Plaintiffs allege that Defendants failed to warn Plaintiffs and their healthcare providers about gadolinium retention and the serious health risks associated with gadolinium-based contrast agents, and failed to disclose the fact that there were safer alternatives.

ii. Bayer's Position

Plaintiffs' lawsuit concerns Bayer's FDA-approved gadolinium-based contrast agent ("GBCA") Magnevist—a product that, along with other GBCAs, has enhanced the quality of hundreds of millions of magnetic resonance imaging ("MRI") scans to help diagnose serious

conditions, including cancer, strokes, and aneurysms. Plaintiffs claim to have developed "Gadolinium Deposition Disease," which is not a "disease" recognized by the medical community and lacks any established diagnostic criteria. Indeed, as Plaintiffs point out in the Complaint, the first time "GDD" appeared in published medical literature was in 2016, in an article relying on "an online presence" of "patient advocacy groups" as well as a "survey" of "17 patients." *See* Semelka et al., Gadolinium in Humans: A Family of Disorders, 207 *American Journal of Roentgenology* 229-31 (2016). Similarly, in defining "GDD" the Complaint cites to "patient advocacy groups" and persons who "sent letters to the FDA." *See* Compl. at p.13-14 ¶¶ 70, 71, Dkt. No. 1 Ex. A, *Geisse v. Bayer HealthCare Pharmaceuticals et al.*, No. 3:17-cv-07026 (Dec. 8, 2017).

The FDA regulates the GBCA products at issue that Plaintiffs claim they used in the United States. Plaintiffs selectively cite that agency's actions to suggest it determined that GDD is a real disease caused by Bayer's medications. The opposite is true. In 2015, the FDA stated that while "trace amounts of gadolinium may stay in the body long-term," the "[a]vailable information ***does not identify any adverse health effects***." *See* 7/27/2015 FDA Safety Announcement, https://www.fda.gov/Drugs/DrugSafety/ucm455386.htm (emphasis added). The FDA reiterated again in December 2017 that "[g]adolinium retention ***has not been directly linked to adverse health effects in patients with normal kidney function***," as Plaintiffs describe themselves as having. *See* 12/19/2017 FDA Safety Announcement, https://www.fda.gov/Drugs/DrugSafety/ucm589213.htm (emphasis added); *see also* Compl. p.7 ¶¶ 40-42, Dkt. No. 1 Ex. A, *Geisse v. Bayer HealthCare Pharmaceuticals et al.*, No. 3:17-cv-07026 (Dec. 8, 2017) (claiming Plaintiffs had "normal or near-normal kidney function prior to developing GDD").

Plaintiffs also take creative liberties in misleadingly recasting decisions made by regulators in other countries around the world, who have no regulatory authority over the GBCAs sold in the United States, as deciding that GDD is a proven phenomenon and that GBCAs cause it. To the contrary, the European Medicines Agency stated as recently as November 23, 2017 that "[t]here is

currently ***no evidence that gadolinium deposition in the brain has caused any harm to patients***," and in no way, shape, or form, validates the existence of "GDD." *See* 11/23/2017 EMA Press Release (emphasis added).[2] The UK's Medicines & Healthcare Products Regulatory Agency likewise said "[t]here is currently ***no evidence*** that ***gadolinium deposition in the brain has caused adverse neurological effects*** in patients," which are the very types of injuries Plaintiffs claim are the hallmark of "GDD." 12/14/2017 Drug Safety Update (emphasis added).[3]

Here, as in the Complaint, Plaintiffs pretend that statements about gadolinium "retention" refer to GDD, though the two phenomena differ radically in that one exists and the other does not. "Retention" means that some of the GBCA product remains behind; standing alone, this suggests no adverse health consequences. According to the plaintiffs in the related lawsuits before this Court, "GDD" symptoms include excessive hair loss, "difficult mentation," dry eyes and mouth, loss of appetite, feeling of dehydration, diarrhea, "spinal issues," "thyroid nodules," arthritis, and more. Not a single regulatory agency, professional association, or medical organization has signed on to the notion that "GDD" is a real disease with any proven health consequences, much less the sweeping symptoms proffered by Plaintiffs in this lawsuit. "GDD," to this day, remains a hypothetical problem born on the internet, and now fueled by this litigation, with no evidence-based support.

B. Principal Factual Issues in Dispute

The principal factual issues in dispute at the present time include the following:

- Whether the defendants had knowledge of the harmful effects of Linear GBCAs
- Whether a safer alternative to Linear GBCAs was available at the relevant times

[2] Available at European Medicines Agency Website, http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/gadolinium_contrast_agents_31/European_Commission_final_decision/WC500240575.pdf.

[3] Available at the UK's Medicines & Healthcare Products Regulatory Agency website, https://www.gov.uk/drug-safety-update/gadolinium-containing-contrast-agents-removal-of-omniscan-and-iv-magnevist-restrictions-to-the-use-of-other-linear-agents.

- Whether the defendants made an intentional decision to market the Linear GBCAs despite having certain knowledge
- Whether GDD is an actual medical condition
- Whether gadolinium-based contrast agents can "cause" GDD
- What health problems, if any, GDD "causes"
- Whether each Plaintiff was administered Magnevist
- Whether each Plaintiff developed what can be "diagnosed" as GDD
- Whether Magnevist "caused" each Plaintiff to develop GDD
- Whether Bayer's product labeling was adequate during the relevant time frame
- Precisely what language Plaintiffs contend should have been, but was not, contained in Bayer's product labeling at the relevant time of Plaintiffs' claimed use
- Whether Plaintiffs' prescribers knew of the relevant risks of Magnevist
- Whether any warnings Plaintiffs claim should have been issued would have changed the prescribing decisions of Plaintiffs' medical providers
- Whether any additional warnings from Plaintiffs' medical providers would have changed Plaintiffs' decisions to undergo the relevant diagnostic procedure
- Whether Magnevist is capable of causing and did in fact cause Plaintiffs' alleged injuries
- Whether Bayer could have foreseen Plaintiffs' alleged injuries at the legally relevant times
- Whether Plaintiffs' claims are barred by the applicable statute of limitations
- Whether Plaintiffs have any admissible proof of general and specific causation
- Whether Plaintiffs have any admissible proof of damages
- Whether any injuries claimed by Plaintiffs were caused by a party other than Bayer
- Whether the Distributing Defendants distributed the Magnevist that was allegedly administered to Plaintiffs

There are likely to be additional factual issues in dispute as the case progresses.

3. Legal Issues

At this early stage, the Parties dispute the following points of law:

A. Plaintiffs' Statement of Disputed Legal Issues

- Whether a U.S. based subsidiary has a duty to collect relevant documents and information from its European parent corporation
- Whether this case was improperly removed under the doctrine of diversity jurisdiction

B. Defendants' Statement of Disputed Legal Issues

- Whether the strict liability and/or negligence claims should be dismissed under Federal Rule of Civil Procedure 12(c) because they fail to allege that Bayer could have foreseen Plaintiffs' alleged injuries. *See, e.g., Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 196 n.6 (2016) (noting that, for "failure to warn liability, . . . the overarching inquiry is whether ***foreseeable*** risks of harm . . . could have been reduced or avoided by warnings").
- If Plaintiffs fail to dismiss these claims as promised herein, whether the fraudulent misrepresentation and/or fraudulent concealment claims should be dismissed under Federal Rule of Civil Procedure 12(c) because Plaintiffs fail to allege that the Bayer could have foreseen Plaintiffs' alleged injuries. *See, e.g., Webb v. Special Elec. Co.*, 63 Cal. 4th 167, 196 n.6 (2016) (noting that, for "failure to warn liability, . . . the overarching inquiry is whether foreseeable risks of harm . . . could have been reduced or avoided by warnings")
- If Plaintiff fails to dismiss these claims as promised herein, whether the fraudulent concealment, fraudulent misrepresentation, and/or negligent misrepresentation counts of the Complaint should be dismissed under Federal Rules of Civil Procedure 9(b) and 12(c) because they fail to name any particular defendant or any particular act

- If Plaintiffs fail to dismiss this claim as promised herein, whether the negligent misrepresentation claim should fail under Federal Rule of Civil Procedure 12(c) because the Complaint fails to plead facts showing that Bayer made any statement "without reasonable ground for believing it to be true," *Nat'l Union Fire Ins. Co. of Pittsburgh, PA v. Cambridge Integrated Servs. Grp., Inc.*, 171 Cal. App. 4th 35, 50 (2009).
- If Plaintiffs fail to dismiss these claims as promised herein, whether the claims under California's Consumer Legal Remedies Act ("CLRA") should be dismissed under Rule 12(c) because the Complaint fails to include facts demonstrating that Bayer violated the Act
- If Plaintiffs fail to dismiss these claims as promised herein, whether the CLRA claims for damages should be dismissed because Plaintiffs failed to provide pre-suit notice required by Cal. Civ. Code § 1782. *See Outboard Marine Corp. v. Superior Court*, 124 Cal. Rptr. 852, 858-59 (Cal. Ct. App. 1975).
- If Plaintiffs fail to dismiss these claims as promised herein, whether the CLRA claims for injunctive relief should be dismissed because Plaintiffs lack standing to seek such relief. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1114 (9th Cir. 2013).
- If Plaintiffs fail to dismiss the negligent misrepresentation, fraudulent concealment, and fraudulent misrepresentation claims as promised herein, whether the prayer for punitive damages should be dismissed under Federal Rule of Civil Procedure 12(c) because the Complaint contains no factual allegations showing that Bayer acted with "oppression, fraud, or malice," Cal. Civ. Code § 3294(a), and because Plaintiffs fail to plead the fraud claims with particularity under Federal Rule of Civil Procedure 9(b). *See Estate of Graham v. Sotheby's, Inc.*, 178 F. Supp. 3d 974, 996 (C.D. Cal. 2016).

4. <u>Motions</u>

Plaintiffs intend to file a motion to remand when permitted to do so by the Court.

At this time, Bayer plans to file the following motions:

- Rule 12(c) motion for judgment on the pleadings for failure to state a claim, and because Plaintiffs lack standing to request injunctive relief under California's Consumer Legal Remedies Act[4]
- Following discovery, motion for summary judgment on any and all claims not supported by the record evidence
- Following discovery, motion to exclude inadmissible expert testimony offered by Plaintiffs

5. Amendment of Pleadings

At this time, Plaintiffs agree to withdraw their claims for fraudulent concealment, fraudulent misrepresentation, negligent representation, and violation of California's Consumer Legal Remedies Act.

Bayer plans to move for judgment on the pleadings with respect to the remaining claims (negligence and strict liability) and Plaintiffs do not allege an independent theory of liability against the Distributing Defendants.

6. Evidence Preservation

The Parties have reviewed the Guidelines Relating to the Discovery of Electronically Stored Information ("ESI Guidelines"), and have met and conferred pursuant to Fed. R. Civ. P. 26(f) regarding reasonable and proportionate steps taken to preserve evidence relevant to the issues reasonably evident in this action. The Parties agree that a written protocol governing the exchange of electronically stored information ("ESI Protocol") will be necessary in this case.

The Parties have agreed to work together to create a mutually agreeable ESI Protocol prior to the commencement of ESI discovery by tailoring the Northern District of California's model stipulated order as appropriate.

[4] If Plaintiffs dismiss their CLRA claims as promised herein, Bayer will not move to dismiss those claims.

7. Disclosures

A. Plaintiffs' Position

Plaintiffs are prepared to make initial disclosures and request simultaneous disclosures by the Defendants.

B. Bayer's Position

Pursuant to Federal Rule of Civil Procedure 26(a)(1)(C), Bayer proposes making initial disclosures on or before 5/1/2018.

8. Discovery

A. Plaintiffs' Position

Plaintiffs contend that there was no jurisdictional discovery completed in *Geisse*.

The parties agree that fact discovery should proceed in *Geisse, et al. v. Bayer, et al.*, Case No. 17-cv-07026-JD. However, Plaintiffs contend that the discovery in *Geisse* will take place in the state court action following remand of this case to the San Francisco Superior Court and designation of that case as a complex case.

Plaintiffs propose that all discovery taken in the *Geisse* case be applicable to the other Related Cases, as well as other currently-filed and future-filed cases. This would include the allowance for cross-noticing of depositions in the federal and state court cases. Given the likelihood of an MDL petition and/or consolidation of cases, it is in the interests of efficiency for the parties to agree to the use of liability and jurisdictional depositions in all cases.

In addition, Plaintiffs propose that the parties agree on a Plaintiff Fact Sheet and Defense Fact Sheet to be utilized in this litigation. Plaintiffs are currently drafting their proposed forms to be circulated to the defendants for review.

Plaintiffs do not agree with Bayer's proposals for "Discovery Limitations and Rules" or Bayer's proposal for a "Discovery Plan" as stated below. These important topics will require further negotiation and discussion at a later date.

B. Bayer's Position

Bayer's position is that Bayer produced jurisdictional discovery regarding Bayer Pharma AG, and Plaintiffs produced preliminary discovery related to Plaintiffs' allegations in the Complaint. As to Plaintiffs' other positions above, Bayer's position is that it is premature to discuss hypothetical MDL petitions not before this Court, cross-noticing of depositions not noticed, or use of "Fact Sheets" that Plaintiffs admit have never been shared with Defendants and are not yet drafted.

i. Anticipated Discovery

Bayer believes that discovery will be needed to address the following subjects:

- Timeliness of the asserted claims
- Product identification
- Plaintiffs' medical diagnoses and bases for same
- Plaintiffs' confounding medical conditions and symptoms and health consequences for same
- Information relied upon when prescribing gadolinium-based contrast agents to patients including Plaintiffs
- Risks and benefits considered when prescribing gadolinium-based contrast agents to patients including Plaintiffs
- Expert discovery on general and specific causation
- Expert discovery on Bayer's regulatory compliance with FDA regulations on reporting and labeling

ii. Discovery Limitations and Rules

Bayer suggests governing discovery as follows:

- Within a reasonable time after a protective order is in place, Bayer agrees to make available the company documents produced in *In re: Gadolinium Contrast Dyes Products Liability Litigation*, MDL No. 1909 and Plaintiffs, in turn, agree to avoid issuing requests that would duplicate such production.
- Plaintiffs are obligated to produce all medical records relevant to the litigation collected to date. Upon request and within five (5) business days, Plaintiffs must provide signed authorization forms for Bayer to collect additional medical records.
- To the extent that either Party collects additional records from Plaintiffs' medical providers to supplement Plaintiffs' production to date, any Party may obtain copies of those additional records by sharing equally in the costs of obtaining and distributing those additional records. Specifically, the Parties must pay half of the costs incurred to obtain additional records and a fair charge to copy or digitize the documents, but only for those records the Parties seek to obtain (to avoid duplication of costs).
- General ESI production requests under Federal Rules of Civil Procedure 34 and 45 shall not include email or other forms of electronic correspondence (collectively "email"). To obtain email parties must propound specific email production requests.
- Email production requests may be propounded only for specific issues, rather than general discovery of a product or business.
- Email production requests must identify the custodian, search terms, and time frame. The parties will cooperate to identify the proper custodians, proper search terms and proper timeframe as set forth in the Guidelines.
- Each requesting party must limit its email production requests to a total of five custodians per producing party for all such requests. The parties may jointly agree to modify this limit without the Court's leave.

- Each requesting party must limit its email production requests to a total of five reasonably tailored search terms per custodian per party. The parties may jointly agree to modify this limit without the Court's leave.
- Because of their limited probative value and significant difficulty of collection, the parties need not produce voicemails or text messages unless good cause exists for seeking these materials from a particular individual on specified subjects within a narrowly tailored period of time.
- No later than 60 days before trial, the parties agree to exchange a Witness Trial List specifying all witnesses that may appear at trial and whether each witness on the Witness Trial List will appear by video or in person.
- Only for treating physicians on the Witness Trial List that have not been previously deposed, if notice is provided to the opposing side within 14 days of service of the Witness Trial List, the Parties agree to permit one fact deposition of such witness(es) to take place no later than 14 days before trial and make reasonable accommodations to facilitate the scheduling of such depositions.

iii. Discovery Plan

Bayer proposes the following discovery plan, which comports with Rule 26(f)(3):

- All proposed deadlines—including for initial disclosures and for the completion of discovery—appear in the chart in Section 17 of this Statement. All proposed changes to the form or requirements of disclosures appear above.
- The subjects of discovery are described above. All proposed "phases" of discovery appear in the chart in Section 17 of this Statement.
- The Parties will propose a stipulated order regarding disclosure of electronically stored information by tailoring the Northern District of California's model order as appropriate.

- The Parties will propose a stipulated protective order regarding confidential information by tailoring the Northern District of California's model order as appropriate.

9. Class Actions

No class action is proposed.

10. Related Cases

The Court has identified the following cases as related to date:

Case No.	Case Name
17-cv-04377-JD	*Davis v. McKesson Corporation*
17-cv-05957-JD	*Faler v. Bracco Diagnostics Inc.*
17-cv-06241-JD	*Esserman v. Bracco Diagnostics, Inc.*
17-cv-06273-JD	*Miller v. GE Healthcare Inc.*
17-cv-06291-JD	*Walton v. GE Healthcare Inc.*
17-cv-06300-JD	*Tucker v. GE Healthcare Inc.*
17-cv-06309-JD	*Goodell v. Bayer HealthCare Pharmaceuticals Inc.*
17-cv-06368-JD	*Montani v. Bracco Diagnostics, Inc.*
17-cv-06369-JD	*Combs v. Bayer HealthCare Pharmaceuticals Inc.*
17-cv-06371-JD	*Gerrity v. McKesson Corporation*
17-cv-06374-JD	*Zelazny v. Bayer HealthCare Pharmaceuticals Inc.*
17-cv-06375-JD	*McGrath v. Bayer Healthcare Pharmaceuticals Inc.*
17-cv-06452-JD	*Lewandowski v. GE Healthcare Inc.*
17-cv-07026-JD	*Geisse, et al v. Bayer Healthcare Pharmaceuticals Inc.*
17-cv-06861-JD	*Sabol v. Bayer Healthcare Pharmaceuticals Inc.*
18-cv-00571-JD	*Munnuru v. Guerbet LLC*

Plaintiffs note that *Young v. Bayer Healthcare Pharmaceuticals, Inc.*, Case No. 18-cv-00811, was recently removed by Bayer and is awaiting assignment to a Northern District Court Judge and is likely to be deemed related and transferred to Your Honor. Plaintiffs intend to file a motion to remand this California resident case to the San Francisco Superior Court.

Bayer notes that *Young v. Bayer Healthcare Pharmaceuticals, Inc.*, Case No. 18-cv-00811-JCS, is not designated as "related" to date and remains pending before the Honorable Susan Illston. Plaintiffs refused to explain how a remand motion in *Young* is relevant here.

11. Relief

Plaintiffs claim special damages for past and future personal injuries, and past and present loss of income and earning capacity, punitive damages, and other available damages. The bases on which Plaintiffs contend damages should be calculated if liability is established are through the acceptable methods of calculation of general damages, special damages, and punitive damages.

All Defendants deny that Plaintiffs are entitled to any damages, including but not limited to compensatory damages, punitive damages, or fees/expenses of any kind.

12. Settlement and ADR

The Parties have not selected an ADR Process at this date. Counsel conferred regarding ADR in compliance with ADR Local Rule 3-5. The Parties agree that the case would not benefit from ADR at this early stage.

Plaintiffs believe the key motion in the case's early stage is the Plaintiffs' motion to remand. Bayer believes that the key motion in the case's early stage is Bayer's motion for judgment on the pleadings.

13. Consent to Magistrate Judge For All Purposes

Whether **all** parties will consent to have a magistrate judge conduct all further proceedings including trial and entry of judgment. ____ YES __X__ NO

14. Other References

This case is ***not*** suitable for reference to binding arbitration, a special master, or the Judicial Panel on Multidistrict Litigation.

15. Narrowing of Issues

Plaintiffs have agreed to voluntarily dismiss the claims for fraudulent misrepresentation, fraudulent concealment, negligent misrepresentation, and for violation of California's Consumer Legal Remedies Act (causes of action 3-6 in Plaintiffs' Complaint).

Bayer intends to file a motion for judgment on the pleadings as to Plaintiffs' remaining claims for negligence and strict liability. If granted, Bayer's motion for judgment on the pleadings listed above would dispose of this case entirely, or alternatively, potentially narrow the claims and/or parties in the case.

16. Expedited Trial Procedure

The Parties agree that this case is not a suitable candidate for handling under the Expedited Trial Procedure.

17. Scheduling

A. Plaintiffs' Position

Counsel for Plaintiffs believe discovery should take place in the state court action following remand of this case to the San Francisco Superior Court. Therefore, Plaintiffs are not in agreement with Bayer's proposed schedule, below.

B. Bayer's Position

Bayer proposes the following schedule of events in the case.

Deadline or Event	Date
All parties' time to file motions to join additional parties	4/2/18
All parties' time to amend pleadings	4/2/18
Plaintiffs shall serve any records or other relevant material in Plaintiffs' possession, custody or control that have not been promised in the September 22, 2017 responses to requests for production but have not been produced to Bayer to date	5/15/18
Mandatory Initial Disclosures (Pursuant to Fed. R. Civ. P. 26(a))	5/1/18
All fact discovery of any kind shall be commenced in time to be completed by this date.	11/15/18
All non-dispositive motions and supporting pleadings (notice of	12/10/18

motion, motion, affidavits, exhibits, memorandum of law, and proposed order), which relate to **fact discovery** and any request for extension of this Pretrial Scheduling Order, shall be filed by this date	
Plaintiffs' disclosure of identity of expert witnesses Pursuant to Rule 26(a)(2)(A)	1/11/19
Defendants' disclosure of identity of expert witness Pursuant to Rule 26(a)(2)(A)	2/11/19
Plaintiffs' full expert disclosures Pursuant to Rule 26(a)(2)(B) accompanied by the written report prepared and signed by the expert witnesses	3/11/19
Defendant full expert disclosures Pursuant to Rule 26(a)(2)(B) accompanied by the written report prepared and signed by the expert witnesses	4/11/19
All discovery, including expert discovery, shall be completed by this date	5/10/19
All non-dispositive motions and supporting pleadings (notice of motion, motion, affidavits, exhibits, memorandum of law, and proposed order), which relate to **expert** discovery and any request for extension of this Pretrial Scheduling Order, shall be filed by this date	5/24/19
All dispositive motions and supporting pleadings (notice of motion, motion, exhibits, affidavits, memorandum of law, and proposed order), including summary judgment and *Daubert* motions, shall be served and filed by this date.	6/24/19
Hearings held on dispositive motions	7/26/19
Pretrial conference	8/23/19
Case shall be ready for trial on or before	9/9/19
Estimate Length of Trial	10-12 Days
Jury/Non-Jury	Jury

18. Trial

The case will be tried to a jury. The Parties estimate the length of trial will be 10-12 days.

19. Disclosure of Non-party Interested Entities or Persons

Each of the Bayer entities has filed the "Certification of Interested Entities or Persons."

In addition to all named parties to the case, Bayer HealthCare Pharmaceuticals Inc. identifies the following entities as having interests that could be substantially affected by the outcome of the proceeding: (1) Schering Berlin Inc., (2) Bayer HealthCare Holdings LLC, (3) Bayer Corporation,

(4) Bayer US Holding LP, (5) Bayer World Investments B.V., (6) Bayer Solution B.V., and (7) Bayer AG.

In addition to all named parties to the case, Bayer Corporation identifies the following entities as having interests that could be substantially affected by the outcome of the proceeding: (1) Bayer US Holding LP, (2) Bayer World Investments B.V., (3) Bayer Solution B.V., and (4) Bayer AG.

In addition to all named parties to the case, Bayer HealthCare LLC identifies the following entities as having interests that could be substantially affected by the outcome of the proceeding: (1) NippoNex Inc., (2) Bayer Medical Care Inc., (3) Bayer West Coast Corporation, (4) Bayer Essure, Inc., (5) Bayer Consumer Care Holdings LLC, (6) Dr. Scholl's LLC, (7) Coppertone LLC, (8) MiraLAX LLC, (9) Bayer HealthCare US Funding LLC, (10) Bayer HealthCare Pharmaceuticals Inc., (11) Bayer East Coast LLC, (12) Schering Berlin Inc., (13) Bayer HealthCare Holdings LLC, (14) Bayer Corporation, (15) Bayer US Holdings LP, (16) Bayer World Investments B.V., (17) Bayer Solution B.V., (18) Bayer AG, and (19) Bayer Pharmaceuticals AG.

In addition to all named parties to the case, McKesson Corporation and McKesson Medical-Surgical identify the following entities as having interests that could be substantially affected by the outcome of the proceeding:

According to their public filings, the following entity, or entities related to such entity, beneficially own more than 10% of McKesson Corporation's outstanding common stock: Wellington Management Group LLP.

McKesson Corporation is a publicly traded company with a large number of outstanding shares, and as such, it would be impracticable to list each individual shareholder. McKesson Medical-Surgical is not publicly traded.

In addition to all named parties to the case, Merry X-Ray Chemical Corporation identifies the following entities as having interests that could be substantially affected by the outcome of the

proceeding: Merry X-Ray Chemical Corporation is a wholly owned subsidiary of Merry X-Ray Corporation, which is a privately held company.

20. Professional Conduct

All attorneys of record for the Parties have reviewed the Guidelines for Professional Conduct for the Northern District of California.

21. Other

A. Plaintiffs' Position on Consolidation of Cases

Plaintiffs contend that the Related Cases should be consolidated for both pre-trial and trial purposes to advance the goal of a fair and efficient resolution of this complex litigation, as described in the Manual for Complex Litigation. *Manual for Complex Litig., 4th* (2016), Part 10, pg. 18. All of the Related Cases involve the same type of drug: Linear Gadolinium-Based Contrast Agents (hereinafter "Linear GBCAs"). Plaintiffs in these cases are not claiming that they were injured by the other type of GBCAs, the Macrocyclic Gadolinium-Based Contrast Agents (hereinafter "Macrocyclic GBCAs"). Plaintiffs' claims in every Related Case include allegations that the Manufacturing Defendants had safer alternative drugs available at all relevant times (Macrocyclic GBCAs), but for reasons to be examined, chose to focus on their less stable and more dangerous Linear GBCAs. Because each of the Related Cases, for all defendants, arise from the following six alleged facts, it is in the interests of judicial efficiency to consolidate the cases for pre-trial and trial purposes. The six central facts are:

1) Plaintiff had normal kidney function prior to an MRI/MRA;
2) Defendants failed to warn that patients with normal kidney function could retain Gadolinium during an MRI/MRA;

3) Defendants failed to warn that Linear GBCAs were less stable than Macrocyclic GBCAs, and are more susceptible to breaking apart and depositing Gadolinium in the patient's tissue, organs, brain, and bones;

4) Plaintiff was administered a Linear GBCA;

5) Plaintiff developed Gadolinium Deposition Disease;

6) Plaintiff was tested and found to have retained Gadolinium, which can only be attributed to the Linear GBCAs, as it does not occur naturally or from other sources.

While Plaintiffs would like to litigate the Related Cases in this forum, it must be noted that a petition to the Judicial Panel for Multidistrict Litigation is anticipated. There have been other similar cases filed in other U.S. District Courts, and in various state courts, as described below, and Plaintiffs are informed that many other cases will be filed. Therefore, some of the argument above may be premature.

As of February 14, 2018, Plaintiffs have identified the following cases pending in other Courts:

Case Name	**Case Number**	**Court**	**Date Filed**
Dwyer v. General Electric Company, et al.	2:18-cv-377	USDC Eastern District of Louisiana	1/6/2017
Simoes v. Guerbet, LLC, et al.	CGC-17-557467	San Francisco Superior Court	3/8/2017
White v. GE Healthcare, Inc., et al.	1:17-cv-00217-SJD	USDC Southern District of Ohio	3/29/2017
Estate of Anessa Muhammad v. Emory Healthcare Inc., et al.	17-A-66058	Atlanta DeKalb County State Court	9/6/2017
Gates v. General Electric Company, et al.	1:16-cv-02614-WYD-NYW	USDC Colorado	10/20/16
Norris v. McKesson Corporation, et al.	CGC-17-562228	San Francisco Superior Court	11/1/2017
Vivacqua v. Bayer AG, et al.	2017-L-13337	Cook County Circuit Court	12/29/2017

B. Defendants' Position on Consolidation of Cases

Particularly given the posture of these cases, Defendants oppose any pre-trial consolidation, which the factors of Rule 42 do not support. Although consolidation is within the discretion of the trial court, *see Inv'rs Research Co. v. U.S. Dist. Court for Cent. Dist. of California*, 877 F.2d 777, 777 (9th Cir. 1989), as a threshold matter, the cases must arise out of a common nucleus of operative facts before consolidation should be considered, *see Seguro de Servicio de Salud v. McAuto Sys. Group*, 878 F.2d 5, 8 (1st Cir. 1989) (overruling consolidation of two arbitrations as an abuse of discretion). Further, consolidation may be denied "if the common issue is not central to the resolution of the cases, or if consolidation will cause delay in the processing of one or more of the individual cases, or will lead to confusion or prejudice in the effective management or trial of one or more of the cases." 9 C. Wright & A. Miller, *Federal Practice and Procedure*, § 2383 (3d ed.)

Pre-trial consolidation of cases is at the very least premature here given every single case is subject to serious challenges as to personal jurisdiction, venue, and proper service. Moreover, each Plaintiff, residing in a different state, alleges different medical symptoms arising from alleged exposures to different GBCAs at different times manufactured by different Defendants. Further, each Plaintiff alleges that the defendant who manufactured the GBCA that Plaintiff received, based on information available to that defendant, failed to warn adequately their respective physician. These factual and legal issues are unique to each Plaintiff and to each Defendant, demonstrating that the cases do not arise out of a common nucleus of operative facts and that consolidation is inappropriate here. *See, e.g., Dunbar v. Medtronic, Inc.*, No. CV 14-01529-RGK AJWX, 2014 WL 3056081, at *3 (C.D. Cal. June 25, 2014) (finding the issues of fact were not common among 29 plaintiffs under Rules 19 and 20).

Consolidating cases for a trial involving over a dozen individual plaintiffs and many non-overlapping defendants, over 6 different pharmaceutical products with different development and

regulatory histories, and varied plaintiff medical conditions and claimed injuries, among other individualized issues, could only serve to unfairly prejudice the defendants and confuse the jury. Plaintiff identifies no cases that have been tried in this fashion or any support for seeking that result here, which Defendants oppose.

Finally, Defendants submit that it is premature to discuss hypothetical MDL petitions not before this Court and deny Plaintiff's misleading presentation above warrants consolidation.

Dated: February 22, 2018 */s/ Todd A. Walburg*

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Attestation: *I, Rodney M. Hudson, hereby attest pursuant to Civil Local Rule 5-1(i)(3) that concurrence in the filing of this document has been obtained from the other signatories.*

/s/ *Rodney M. Hudson*

CASE MANAGEMENT ORDER

The above JOINT CASE MANAGEMENT STATEMENT & PROPOSED ORDER is approved as the Case Management Order for this case and all parties shall comply with its provisions.

IT IS SO ORDERED.

Dated:

UNITED STATES DISTRICT/MAGISTRATE JUDGE